UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,290	08/03/2001	David M. Goldenberg	018733-1012	5316

22428 7590 12/16/2003

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	6

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/921,290	GOLDENBERG, DAVID M.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-28,32-39 and 41-48* is/are rejected.

7)☒ Claim(s) *13 and 29-31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II (claims 1-3, 5-8, 10, 11, 13-21 and 23-48 in Paper No. 5, received September 30, 2003 is acknowledged. The traversal is on the ground(s) that the antibodies used in the claimed invention are specific to the same antigens and would target the same cell types, regardless of the disorder. This argument has been found persuasive. Accordingly, all pending claims will be examined.

2. Claims 1-48 are pending.

Claims 1-48 are examined on the merits.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the U.S. application 09/038,955, filed March 12, 1998, now U.S. patent 6,183,744, which is a continuation in part of 09/307,816, filed May 10, 1999, now U.S. 6,306,393 upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for all the claims of this application. These applications only contemplate the treatment of B-cell disorders (including plasma-cell disorders), hence the priority afforded the examined claims is the effective filing date of the instant application, August 3, 2001.

4. The first line of the specification lacks the necessary reference to prior applications. A statement reading "This application claims priority to U.S. Application

09,038,955, filed 03/12/1998, now U.S. Patent 6,183,744, which is a continuation in part of U.S. Application 09/307,816, filed May 10, 1999, now U.S. Patent 6,306,393." should be entered following the title of the invention or as the first sentence of the specification.

Oath/Declaration

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: it lists an improper U.S. Parent application number. The **correct** application number is "**09/038,955**" and not "09/038,995". Applicant should also list the corresponding patent numbers for both parent applications.

Claim Rejections - 35 USC § 112

6. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 4 is vague and indefinite in the phrase "shows higher specificity for tumors of these cells as compared to their normal counterparts". It is not clear what cells Applicant is referencing and what is regarded as higher specificity and it is not clear how that is determined. Furthermore, the recitation, these cells lacks proper antecedent bases. Correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1, 3-5, 9, 11, 12, 16, 19-22, 26, 39-41, 43 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 5,776,456 (filed June 7, 1995). U.S. Patent #5,776,456 teaches "...therapeutic methods designed for the treatment of B cell disorders, and in particular, B cell lymphomas", which is a B cell malignancy, see column 5, lines 12-23. The protocols are based upon the administration of diagnostic "imaging" radiolabeled anti-CD20 antibodies, see column 9, lines 36-40.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-12, 14-27, 32, 37-39 and 41-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-22, 25, 32 and 33 of U.S. Patent No. 6,306,393 (issued October 23, 2001). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent teaches a method for treating a subject with a B-cell malignancy with a therapeutic composition comprising a pharmaceutically acceptable carrier and at least one antibody, wherein the antibody component is a naked antibody. Furthermore, the disclosed method reveals that the antibody component may comprise an antibody (i.e. naked, multispecific), fusion protein and/or immunoconjugate (i.e. radiolabel, cytokine, chemotherapeutic drug). These limitations read on the claimed invention.

11. Claims 1-12, 14-27 and 32-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-22, 25, 32 and 33 of U.S. Patent No. 6,306,393, in view of U.S. Patent No. 5,837,242 (May 14,

1996). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent teaches a method for treating a subject with a B-cell malignancy with a therapeutic composition comprising a pharmaceutically acceptable carrier and at least one antibody, wherein the antibody component is a naked antibody. Furthermore, the disclosed method reveals that the antibody component may comprise an antibody (i.e. naked, multispecific), fusion protein and/or immunoconjugate (i.e. radiolabel, cytokine, chemotherapeutic drug). These limitations read on the claimed invention.

Patent '393 does not teach wherein the antibody component comprises a bispecific antibody with an arm that is specific for a low-molecular weight hapten with an attached therapeutic agent. However, patent '242 teaches the use of bispecific antibodies in the recruitment of powerful effector functions of cytotoxic T cells or natural killer (NK) cells, as well as a tool for imaging tumors, see column 20, lines 61-63; column 21, lines 15-30. It would have been *prima facie* obvious to couple a bispecific antibody with a pharmaceutically acceptable carrier in order to treat a B cell disorder in an animal.

14. Claims 1-12, 14-28, 32, 37-39 and 41-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-22, 25, 32 and 33 of U.S. Patent No. 6,306,393 in view of Rybak et al. (Proc. Nat. Acad. Sci. USA 89:3165-3169, April 1992). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent teaches a

method for treating a subject with a B-cell malignancy with a therapeutic composition comprising a pharmaceutically acceptable carrier and at least one antibody, wherein the antibody component is a naked antibody. Furthermore, the disclosed method reveals that the antibody component may comprise an antibody (i.e. naked, multispecific), fusion protein and/or immunoconjugate (i.e. radiolabel, cytokine, chemotherapeutic drug). These limitations read on the claimed invention.

Patent '393 does not teach wherein the therapeutic composition comprises a combination of a naked antibody and a RNase toxin immunoconjugate. However, Rybak teaches the use of chimeric antibodies linked to toxins such as RNase to target tumor cells, see page 3165, abstract and Introduction. It would have been *prima facie* obvious to add a RNase toxin to the taught antibody composition because the cytotoxic potential of the toxin is increased and functional experiments have proven tumor growth inhibitory activity.

12. Claims 1-12, 14-27, 32, 37-39 and 41-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-13, 15-19 and 23 of U.S. Patent No. 6,183,744 (issued February 6, 2001). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent teaches a method for treating a subject with a B-cell malignancy with a therapeutic composition comprising a pharmaceutically acceptable carrier and at least one antibody, wherein the antibody component is a naked antibody. Furthermore, the disclosed method reveals that the antibody component may comprise an antibody

(i.e. naked, multispecific), fusion protein and/or immunoconjugate (i.e. radiolabel, cytokine, chemotherapeutic drug). These limitations read on the claimed invention.

13. Claims 1-12, 14-27 and 32-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-13, 15-19 and 23 of U.S. Patent No. 6,183,744 (issued February 6, 2001), in view of U.S. Patent No. 5,837,242 (May 14, 1996). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent teaches a method for treating a subject with a B-cell malignancy with a therapeutic composition comprising a pharmaceutically acceptable carrier and at least one antibody, wherein the antibody component is a naked antibody. Furthermore, the disclosed method reveals that the antibody component may comprise an antibody (i.e. naked, multispecific), fusion protein and/or immunoconjugate (i.e. radiolabel, cytokine, chemotherapeutic drug). These limitations read on the claimed invention.

Patent '393 does not teach wherein the antibody component comprises a bispecific antibody with an arm that is specific for a low-molecular weight hapten with an attached therapeutic agent. However, patent '242 teaches the use of bispecific antibodies in the recruitment of powerful effector functions of cytotoxic T cells or natural killer (NK) cells, as well as a tool for imaging tumors, see column 20, lines 61-63; column 21, lines 15-30. It would have been *prima facie* obvious to couple a bispecific antibody with a pharmaceutically acceptable carrier in order to treat a B cell disorder in an animal.

20. Claims 1-12, 14-28, 32, 37-39 and 41-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-22, 25, 32 and 33 of U.S. Patent No. 6,183,744 (issued February 6, 2001), in view of Rybak et al. (Proc. Nat. Acad. Sci. USA 89:3165-3169, April 1992). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent teaches a method for treating a subject with a B-cell malignancy with a therapeutic composition comprising a pharmaceutically acceptable carrier and at least one antibody, wherein the antibody component is a naked antibody. Furthermore, the disclosed method reveals that the antibody component may comprise an antibody (i.e. naked, multispecific), fusion protein and/or immunoconjugate (i.e. radiolabel, cytokine, chemotherapeutic drug). These limitations read on the claimed invention.

Patent '744 does not teach wherein the therapeutic composition comprises a combination of a naked antibody and a RNase toxin immunoconjugate. However, Rybak teaches the use of chimeric antibodies linked to toxins such as RNase to target tumor cells, see page 3165, abstract and Introduction. It would have been *prima facie* obvious to add a RNase toxin to the taught antibody composition because the cytotoxic potential of the toxin is increased and functional experiments have proven tumor growth inhibitory activity.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

(703) 306-5880. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4315.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
12 December 2003